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DOCKET NO.: B0801.70256US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Pier et al.  
Serial No.: 10/712,391  
Confirmation No.: 8225  
Filed: November 12, 2003  
For: METHODS AND PRODUCTS FOR TREATING STAPHYLOCOCCAL  
INFECTIONS  
Examiner: Not Yet Assigned  
Art Unit: 1645

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 23<sup>rd</sup> day of May, 2005.

Kristin J. Ketelhut  
Kristin J. Ketelhut

**MAIL STOP AMENDMENT**

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Pier et al., Applicant*

By:

Maria A. Trevisan

Maria A. Trevisan, Reg. No.: 48,207  
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Telephone: (617) 646-8000

Docket No.: B0801.70256US01

Date: May 25, 2005

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*Kristin J. Ketelhut*  
Kristin J. Ketelhut

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF**  
**DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
B0801.70300US01	11/111,688	April 21, 2005	Pier et al.

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication(s)</u>
B0801.70256WO00	PCT/US03/36371	April 13, 2005	Invitation to Pay Additional Fees

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Pier et al., Applicant*

By:

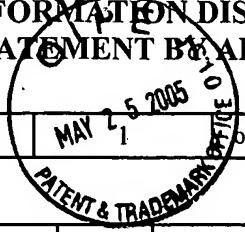


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FORM PTO-1449/A and B (Modified) <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Sheet <b>MAY 25 2005</b> of <b>7</b>		APPLICATION NO.: 10/712,391	ATTY. DOCKET NO.: B0801.70256US01
		FILING DATE: November 12, 2003	CONFIRMATION NO.: 8225
		APPLICANT: Pier et al.	
		GROUP ART UNIT: 1645	EXAMINER: Not Yet Assigned

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	4,197,290		Yoshida	04-08-1980
	A2	4,285,936		Pier et al.	08-25-1981
	A3	4,443,549		Sadowski	04-17-1984
	A4	4,578,458		Pier	03-25-1986
	A5	4,652,448		Sadowski	03-24-1987
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	A7	4,789,735		Frank et al.	12-06-1988
	A8	4,795,803		Lindberg et al.	01-03-1989
	A9	4,830,852		Marburg et al.	05-16-1989
	A10	4,859,449		Mattes	08-22-1989
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#### FOREIGN PATENT DOCUMENTS

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		Office/ Country	Number	Kind Code			
	B1	EP	0 302 781	A1	Institut Pasteur	02-08-1989	Y- Abstr.

FORM PTO-1449/A and B (Modified) <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/712,391	ATTY. DOCKET NO.: B0801.70256US01		
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Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
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	B2	EP	0 694 309	A2	Kitasato Institute	10-31-1996	
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	B5	FR	2 640 628	A1	Commissariat A L'Energie Atomique	12-16-1988	Y - Abstr.
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	B21	WO	2004/043407	A2	The Brigham and Women's Hospital, Inc.	05-27-2004	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C5	GENBANK Submission; NIH/NCBI, Accession No. BA000018; Kuroda et al.; October 22, 2004 (last submission).	
	C6	[No Author Listed] ATCC Catalogue website 2001; ATCC Number 35984.	
	C7	[No Author Listed] ATCC Catalogue: Bacteria and Bacteriophages; 1992; 18th Edition; p301.	
	C8	AMMENDOLIA et al., Slime production and expression of the slime-associated antigen by staphylococcal clinical isolates. J Clin Microbiol. 1999 Oct;37(10):3235-8.	
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	C10	BERNSTEIN, et al., Antibody coated bacteria in otitis media with effusions. Ann Otol Rhinol Laryngol Suppl. 1980 May-Jun;89(3 Pt 2):104-9. Abstract only.	
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	C12	CHANTER, Partial purification and characterization of two non K99 mannose-resistant haemagglutinins of Escherichia coli B41. J Gen Microbiol. 1983 Jan;129(1):235-43.	

<b>FORM PTO-1449/A and B (Modified)</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/712,391	ATTY. DOCKET NO.: B0801.70256US01
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	C13	CHEN et al., Characterization and biological properties of chemically deglycosylated human chorionic gonadotropin. Role of carbohydrate moieties in adenylyl cyclase activation. <i>J Biol Chem.</i> 1982 Dec 10;257(23):14446-52.	
	C14	CHRISTENSEN et al., Adherence of slime-producing strains of <i>Staphylococcus epidermidis</i> to smooth surfaces. <i>Infect Immun.</i> 1982 Jul;37(1):318-26.	
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	C17	CONLON et al., Regulation of icaR gene expression in <i>Staphylococcus epidermidis</i> . <i>FEMS Microbiol Lett.</i> 2002 Nov 5;216(2):171-7.	
	C18	CRAMTON et al., The intercellular adhesion (ica) locus is present in <i>Staphylococcus aureus</i> and is required for biofilm formation. <i>Infect Immun.</i> 1999 Oct;67(10):5427-33.	
	C19	DOBRIN, et al., The role of complement, immunoglobulin and bacterial antigen in coagulase-negative staphylococcal shunt nephritis. <i>Am J Med.</i> 1975 Nov;59(5):660-73. Abstract only.	
	C20	ELDER et al., Characterization of monoclonal antibodies specific for adhesion: isolation of an adhesin of <i>Streptococcus sanguis</i> FW213. <i>Infect Immun.</i> 1986 Nov;54(2):421-7.	
	C21	ESPERSEN, et al., Solid-phase radioimmunoassay for IgG antibodies to <i>Staphylococcus epidermidis</i> . Use in serious coagulase-negative staphylococcal infections. <i>Arch Intern Med.</i> 1987 Apr;147(4):689-93. Abstract only.	
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	C26	FOURNIER et al., Purification and characterization of <i>Staphylococcus aureus</i> type 8 capsular polysaccharide. <i>Infect Immun.</i> 1984 Jul;45(1):87-93.	
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	C29	HEILMANN et al., Molecular basis of intercellular adhesion in the biofilm-forming <i>Staphylococcus epidermidis</i> . <i>Mol Microbiol.</i> 1996 Jun;20(5):1083-91.	
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	C33	ICHIMAN et al., Induction of resistance with heat-killed unencapsulated strains of <i>Staphylococcus epidermidis</i> against challenge with encapsulated strains of <i>Staphylococcus epidermidis</i> . <i>Microbiol Immunol.</i> 1989;33(4):277-86.	
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	C35	ICHIMAN et al., Specificity of monoclonal antibodies against an encapsulated strain of <i>staphylococcus epidermidis</i> . in <i>The Staphylococci</i> , <i>Zbl Bakt.</i> 1991;Suppl 21:150-2.	
	C36	JEFFERSON et al., Identification of a 5-nucleotide sequence that controls expression of the ica locus in <i>Staphylococcus aureus</i> and characterization of the DNA-binding properties of IcaR. <i>Mol Microbiol.</i> 2003 May;48(4):889-99.	
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	C38	JOHNSON et al., Interference with granulocyte function by <i>Staphylococcus epidermidis</i> slime. <i>Infect Immun.</i> 1986 Oct;54(1):13-20.	
	C39	KELLY-QUINTOS et al., Biological Characterization of Fully Human Monoclonal Antibodies to <i>Staphylococcal</i> Surface Polysaccharide PNAG. Abstracts of the 104th General Meeting of the American Society for Microbiology. <i>Am Soc Microbiol.</i> 2004 May;abstract A-63. Abstract and corresponding presentation.	
	C40	KEUTMANN et al., Evidence for a conformational change in deglycosylated glycoprotein hormones. <i>FEBS Lett.</i> 1985 Jun 17;185(2):333-8.	
	C41	KOHLER, Derivation and diversification of monoclonal antibodies. <i>Science.</i> 1986 Sep 19;233(4770):1281-6.	
	C42	KOJIMA et al., Antibody to the capsular polysaccharide/adhesin protects rabbits against catheter-related bacteremia due to coagulase-negative <i>staphylococci</i> . <i>J Infect Dis.</i> 1990 Aug;162(2):435-41.	
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	C48	LUDWICKA et al., Investigation on extracellular slime substance produced by <i>Staphylococcus epidermidis</i> . <i>Zentralbl Bakteriol Mikrobiol Hyg [A].</i> 1984 Dec;258(2-3):256-67.	
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	C52	MACK et al., Essential functional role of the polysaccharide intercellular adhesin of <i>Staphylococcus epidermidis</i> in hemagglutination. <i>Infect Immun.</i> 1999 Feb;67(2):1004-8.	
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	C55	MAIRA-LITRAN et al., Synthesis and Immunological Properties of a Staphylococcal Deacetylated-poly-N-acetyl Glucosamine (dPNAG) Polysaccharide and Clumping Factor A (ClfA) Protein Conjugate Vaccine. Abstracts of the 104th General Meeting of the American Society for Microbiology. Am Soc Microbiol. 2004 May;abstract E-062. Abstract and corresponding presentation.	
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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICATION NO.: 10/712,391	ATTY. DOCKET NO.: B0801.70256US01
		FILING DATE: November 12, 2003	
		APPLICANT: Pier et al.	
		GROUP ART UNIT: 1645	EXAMINER: Not Yet Assigned

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/712,391	ATTY. DOCKET NO.: B0801.70256US01
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	C91	ZIEBUHR et al., A novel mechanism of phase variation of virulence in <i>Staphylococcus epidermidis</i> : evidence for control of the polysaccharide intercellular adhesin synthesis by alternating insertion and excision of the insertion sequence element IS256. <i>Mol Microbiol</i> . 1999 Apr;32(2):345-56.	

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